REMARKS

Claims 33-51 are pending in this application. Claim 1-16 were canceled previously. Claims 17-32 were withdrawn previously. No claims have been amended. No claims have been added or canceled. No new matter has been added.

Withdraw of all currently applied rejections is respectfully requested for at least the reasons set forth below.

Allowable Subject Matter

Applicants appreciate that dependent claims 44-46 would be allowable if the rejections of those claims under §112 are addressed and the claims were rewritten into independent form to include the limitations of the base claim and any intervening claims.

Applicants believe that, in light of the arguments set forth below regarding the §112 and §102 rejections of the independent claim 33, all pending claims are patentable and allowance of all pending claims is respectfully requested.

Prior Art Claim Rejections

Claims 33, 37, 38 and 43 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0157337 (Burke, et al., hereinafter "Burke").

Claims 33, 36, and 42 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,223,365 (Freiherr Von Der Goltz, hereinafter "Freiherr").

Claims 33-35, 37, 39, 47 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,494,639 (Grzegorzewski).

Claims 48-50 are rejected under 35 U.S.C. §103(a) as being unpatentable over Freiherr Von Der Goltz in view of U.S. Patent No. 6,673,622 (Jina).

Claims 48 and 51 are rejected under 35 U.S.C. §103(a) as being unpatentable over Freiherr Von Der Goltz in view of U.S. Patent Application Publication No. 2004/0072357 (Stiene).

Claim 41 is rejected under 35 U.S.C. §103(a) as being unpatentable over Freiherr Von Der Goltz.

Claim 40 is rejected under 35 U.S.C. §103(a) as being unpatentable over Burke in view of U.S. Patent Application Publication No. 2004/0054283 (Corey).

Applicants respectfully traverse these rejections.

As stated above, the office action contends that Burke anticipates claim 33. Applicants note that Burke has a filing date of October 17, 2003. As stated in the cross-reference paragraph of the as-filed specification, the current application claims the benefit of U.S. Provisional Application No. 60/463,557 filed on April 16, 2003. Therefore, Burke cannot be considered prior art against the current application. Also, Applicants note that Burke claims the benefit of U.S. Provisional Application No. 60/480,298 filed on June 20, 2003. Therefore, U.S. Provisional Application No. 60/480,298 cannot be considered prior art against the current application. Applicants further note that Burke is a continuation-in-part that claims the priority benefit of a series of inter-related applications, the most recent of which was filed on October 4, 2002. Burke's specification is different from the specification of the application filed on October 4, 2002. Also, the citations the office action makes to Burke in the rejections of the pending claims are not present in the specification of the application filed on October 4, 2002. Applicants make no assertion regarding the patentability of the pending claims in light of the application filed on October 4, 2002 or any of the related, but earlier filed, applications.

Accordingly, because Burke cannot be prior art against the current application, Applicants respectfully request that the §102(e) rejection of claim 33 over Burke be reconsidered and withdrawn.

The office action reiterates the contention that Grzegorzewski anticipates claim 33. Specifically, the office action contends that Grzegorzewski's piezoelectric element 8 is ***a signal driver in communication with the transducer element, wherein the signal driver applies a signal to the transducer element, and wherein the signal driver varies a value of the signal***. With all due respect to the contentions in the office action, Applicants respectfully disagree because Grzegorzewski's piezoelectric element 8 is not a signal driver. Therefore, Grzegorzewski's piezoelectric element 8 cannot apply a signal to the transducer element and vary the value of the signal.

The claimed embodiments contemplate that, in order to determine blood characteristics like coagulation properties, an electronic section or a signal processing section of a sensor excites a transducer over a frequency range. The frequency range may vary from a single KHz to several GHz to detect changes in the operational parameters of the transducer. These changes reflect the response of the blood sample to the introduced acoustic waves. The detected changes include variations in the transfer function, the resonant frequency, the resonant amplitude, the phase and the quality factor. These measured changes in the operational parameters are processed, related to the targeted blood property (the characteristic coagulation factors for instance), and displayed.

Accordingly, the signal processor comprises a system of accompanying electrical oscillatory circuits in which resonant transducer structures ***control their frequency, phase and the amplitude***. Thus, the signal processing section or the electronic section is capable of acting as a signal driver to excite the transducer over a range of frequencies, phases and amplitudes in a controlled and predetermined manner.

Grzegorzewski's piezoelectric element 8 is not a signal driver. Grzegorzewski generally describes a device to measure changes in the viscosity and/or density in a test fluid. A test fluid is introduced through port 11 into a measuring chamber 7 and exposed to a reaction component located on a substrate 13. The reaction between the test fluid and the reaction component includes vibrations that are detected by a piezoelectric element 8. The piezoelectric element 8 converts the reaction effect into an electrical signal that is transmitted through the electrodes 14 that are attached to the piezoelectric element 8. The electrical signal is transmitted from the electrodes 14 to an oscillator circuit 51 via terminals 16 and conductors 15. A microprocessor 52 determines the oscillating frequency of the oscillator circuit 51. The microprocessor 52 then determines the measured values of the test fluid based on the oscillating frequency. See the Abstract and column 4, lines 22-62 and column 6, lines 3-20 of Grzegorzewski

Grzegorzewski's piezoelectric element 8 is not a signal driver. The piezoelectric element 8 functions as a transducer which converts the vibrations created from the reaction of the test fluid with the reaction component in chamber 7 into a signal that is transmitted through the electrodes 14. The piezoelectric element 8 is not ***controlling*** the frequency, phase or amplitude of the signal to the electrodes 14. The frequency, phase and amplitude of

the electric signal are an uncontrolled function of the reaction in the chamber 7. The piezoelectric element 8 is merely slavishly converting the vibrations created from the reaction in the chamber 7 into an electric signal. The oscillator 51 is then excited by the signal it receives from the electrodes 14 and the microprocessor 52 determines the oscillation frequency of the oscillator 51.

Therefore, Grzegorzewski does not disclose or suggest a signal driver in communication with the transducer element, wherein the signal driver applies a signal to the transducer element, and wherein the signal driver varies a value of the signal. Accordingly, Applicants respectfully request that the §102(b) rejection of claim 33 over Grzegorzewski be reconsidered and withdrawn.

The office action reiterates the contention that Freiherr anticipates claim 33. On page 8, the office action states that in the previous response, Applicants argue that Freiherr does not disclose applying a signal and measuring a blood characteristic in response to the signal Applicants never asserted that Freiherr does not disclose or suggest "applying a signal." Applicants did assert in the previous response that Freiherr does not disclose or suggest **a *signal processor in communication with a transducer element that determines a characteristic of the blood as a function of the blood's response to a signal.***

On page 3, the office action restates the previous rationale for the §102(e) rejection of claim 33. Specifically, the office action restates that Freiherr's elements 9 and 18 disclose a signal processor in connection with the transducer for determining a blood characteristic from the blood's response to the varying signal. Applicants' argument in the previous response was that Freiherr's elements 9 and 18 did not disclose a signal processor in communication with a transducer element that determines a characteristic of the blood as a function of the blood's response to a signal. The present office action states on page 8 that the resulting change in pressure and flow velocity are measured to determine the characteristics of the blood. The office action also cites Freiherr's column 9, lines 31-47.

With all due respect to the contentions in the office action, Applicants respectfully disagree because Freiherr's elements 9 and 18 are not a signal processor that determines the hemostasis functions of the blood as a function of the blood's response to a signal. Also, Freiherr's column 9, lines 31-47 do not disclose or suggest a signal processor that determines the hemostasis functions of the blood as a function of the blood's response to a signal.

Freiherr determines the hemostasis functions of whole blood or plasma. (*Freiherr* - Abstract). Freiherr's Figures 25-29 show examples of the hemostasis functions of the blood or plasma sample that are determined as a result of measurements taken. In operation, Freiherr discloses that the controller 18 controls the drive of motor 17, which in turn controls the motion of piston 4. The manipulation of piston 4 affects the pressure of the sample in the pressure gauge chamber 3. The pressure gauge 9 is connected to the pressure gauge chamber 3 to measure the pressure of chamber 3. The pressure gauge 9 is also connected to the controller 18 so that the controller 18 can control the movement of piston 4 (through motor 17) as a function of the pressure measured by pressure gauge 9. (*Freiherr* - column 10, lines 11-46).

While the controller 18 measures the change in pressure in chamber 3 via the pressure gauge 9, the controller 18 does *not* determine a characteristic (hemostasis function) of the blood or plasma sample as a function of that pressure change measurement. Freiherr does *not* disclose or suggest that the controller 18 is capable of the analysis required to be made with the various measurements to determine the hemostasis functions of the blood or plasma as those functions are disclosed in Freiherr's Figures 25-29. Further, Freiherr does *not* disclose or suggest that the controller 18 has the capability to measure the other variables required to determine the hemostasis functions such as the volume in the cylinder 25 ***or the volumetric flow through the reaction device 39*** after a certain predetermined time has elapsed. (*Freiherr* - column 6, lines 57-60). Thus, the pressure gauge 9 and the controller 18 cannot determine the hemostasis function of the blood or plasma. Therefore, Freiherr does ***not*** disclose or suggest a signal processor that determines a characteristic of the blood as a function of a response of the blood to a signal.

The section of Freiherr cited by the office action in rebuttal to Applicants' previous arguments discloses or suggests nothing about a signal processor in communication with a transducer element that determines a characteristic of the blood as a function of the blood's response to a signal. In the cited section, Freiherr recites as follows:

> The particular reaction site (reaction opening) of reaction device 39 may be designed in such a way that blood components, in particular thrombocytes, adhere and aggregate there, thereby partially or totally clogging the

> reaction opening. The cross section of the flow provided in the reaction opening is thereby narrowed, resulting in increased flow resistance. A conveyor pressure corresponding to the pressure difference between a pressure, in particular suction pressure, generated by a conveyor device, and the external pressure (atmospheric pressure) acts on the blood to be examined which is present in storage chamber 15. This conveyor pressure is altered during the cross-sectional narrowing of the reaction opening as a result of the possible deposition and aggregation of thrombocytes, or by a reduction in the flowability of the blood caused by the onset of global, in particular primary, blood coagulation, and thus, increased flow resistance. (Freiherr column 9, lines 31-47).

Accordingly, Applicants respectfully request that the §102(e) rejection of claim 33 over Freiherr be reconsidered and withdrawn.

Applicant believes that the dependent claims 34-43 and 47-51 are patentable for at least the reason that the dependent claims depend from a patentable base claim and recite further patentable elements. Accordingly, Applicant respectfully requests that the §103(a) rejections of claims 34-43 and 47-51 be reconsidered and withdrawn.

Claim Rejections Under 35 U.S.C. §112

Claims 33-51 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the office action states that the phrase "biological sensing media" is not defined in the specification or claims and is also not present in the specification or in the as-filed claims. Applicants traverse this rejection.

Applicants are not aware of any requirement for an exact quote of the claimed subject matter in the narrative of the specification or in the figures. Also, Applicants are not certain what is meant by the office action's reference to a "direct connection." However, the meaning of "direct connection" notwithstanding, Applicants contend that there is, in fact, support for the claimed subject matter in the specification, as asserted in the previous response and repeated here as follows:

In addition to the reference to "bio-sensing element" in Figure 2, on page 25, lines 24-33 of the original specification, it is stated:

> Thereafter, the blood sample is exposed to a sensing element, preferably a biologically active substance such as collagen or thromboplastin, which is selectively responsive to a measurand of interest such as platelets, blood cells, or a selected protein. When the biomeasurand interacts with the sensing element, microscopic physical, chemical, and/or biochemical changes are produced. These microscopic changes cause the macroscopic physical changes in the biosensing element, which are converted by the acousto-mechanical transducer into a measurable electric signal output.

Support for the phrase "biological sensing media" in claim 33 can be drawn from the referenced "bio-sensing element" in Figure 2, from the referenced biologically active substance, sensing element and biosensing element in the above cited. Therefore, there is adequate support in the original specification for the phrase "biological sensing media."

Therefore, Applicants contend that the claimed subject matter "biological sensing media" is clearly and sufficiently supported by the as-filed specification. Accordingly, Applicants respectfully request that the §112 rejections of claims 33-51 be reconsidered and withdrawn.

Conclusion

Insofar as the Examiner's rejections having been adequately addressed, Applicants believe that the current application, including claims 33-51, is in condition for allowance and such action is respectfully requested.

The Examiner is invited to call the Applicants' undersigned representative to discuss this application should the Examiner determine such a discussion would facilitate the application's allowance.

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